AUTHORITY: 21 U.S.C. 321, 342, 348, 371.

SOURCE: 42 FR 14653, Mar 15, 1977, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 184 appear at 66 FR 56035, Nov. 6, 2001, 66 FR 66742, Dec. 27, 2001, 68 FR 15355, Mar. 31, 2003, 69 FR 13717, Mar. 24, 2004, 70 FR 40880, July 15, 2005, and 70 FR 67651, Nov. 8, 2005.

Subpart A—General Provisions

§ 184.1 Substances added directly to human food affirmed as generally recognized as safe (GRAS).

(a) The direct human food ingredients listed in this part have been reviewed by the Food and Drug Administration and determined to be generally recognized as safe (GRAS) for the purposes and under the conditions prescribed. The regulations in this part shall sufficiently describe each ingredient to identify the characteristics of the ingredient that has been affirmed as GRAS and to differentiate it from other possible versions of the ingredient that have not been affirmed as GRAS. Ingredients affirmed as GRAS in this part are also GRAS as indirect human food ingredients, subject to any limitations prescribed in parts 174, 175, 176, 177, 178 or § 179.45 of this chapter or in part 186 of this chapter. The purity specifications in this part do not apply when the ingredient is used in indirect applications. However, when used in indirect applications, the ingredient must be of a purity suitable for its intended use in accordance with § 170.30(h)(1) of this chapter.

(b) Any ingredient affirmed as GRAS in this part shall be used in accordance with current good manufacturing practice. For the purpose of this part, current good manufacturing practice includes the requirements that a direct human food ingredient be of appropriate food grade; that it be prepared and handled as a food ingredient; and that the quantity of the ingredient added to food does not exceed the amount reasonably required to accomplish the intended physical, nutritional, or other technical effect in food.

(1) If the ingredient is affirmed as GRAS with no limitations on its conditions of use other than current good manufacturing practice, it shall be regarded as GRAS if its conditions of use are consistent with the requirements of paragraph (b), (c), and (d) of this section. When the Food and Drug Administration (FDA) determines that it is appropriate, the agency will describe one or more current good manufacturing practice conditions of use in the

regulation that affirms the GRAS status of the ingredient. For example, when the safety of an ingredient has been evaluated on the basis of limited conditions of use, the agency will describe in the regulation that affirms the GRAS status of the ingredient, one or more of these limited conditions of use, which may include the category of food(s), the technical effect(s) or functional use(s) of the ingredient, and the level(s) of use. If the ingredient is used under conditions that are significantly different from those described in the regulation, that use of the ingredient may not be GRAS. In such a case, a manufacturer may not rely on the regulation as authorizing that use but shall independently establish that that use is GRAS or shall use the ingredient in accordance with a food additive regulation. Persons seeking FDA approval of an independent determination that a use of an ingredient is GRAS may submit a GRAS petition in accordance with §170.35 of this chapter.

(2) If the ingredient is affirmed as GRAS with specific limitation(s), it shall be used in food only within such limitation(s), including the category of food(s), the functional use(s) of the ingredient, and the level(s) of use. Any use of such an ingredient not in full compliance with each such established limitation shall require a food additive regulation.

(3) If the ingredient is affirmed as GRAS for a specific use, without a general evaluation of use of the ingredient, other uses may also be GRAS.

(c) The listing of a food ingredient in this part does not authorize the use of such substance in a manner that may lead to deception of the consumer or to any other violation of the Federal Food, Drug, and Cosmetic Act (the Act).

(d) The listing of more than one ingredient to produce the same technological effect does not authorize use of a combination of two or more ingredients to accomplish the same technological effect in any one food at a combined level greater than the highest level permitted for one of the ingredients.

(e) If the Commissioner of Food and Drugs is aware of any prior sanction for use of an ingredient under conditions different from those proposed to be affirmed as GRAS, he will concurrently propose a separate regulation covering such use of the ingredient under part 181 of this chapter. If the Commissioner is unaware of any such applicable prior sanction, the proposed regulation will so state and will require any person who intends to assert or rely on such sanction to submit proof of its existence. Any regulation promulgated pursuant to this section constitutes a determination that excluded uses would result in adulteration of the food in violation of section 402 of the Act, and the failure of any person to come forward with proof of such an applicable prior sanction in response to the proposal will constitute a waiver of the right to assert or rely on such sanction at any later time. The notice will also constitute a proposal to establish a regulation under part 181 of this chapter, incorporating the same provisions, in the event that such a regulation is determined to be appropriate as a result of submission of proof of such an applicable prior sanction in response to the proposal.

(f) The label and labeling of the ingredient and any intermediate mix of the ingredient for use in finished food shall bear, in addition to the other labeling required by the Act:

(1) The name of the ingredient, except where exempted from such labeling in part 101 of this chapter.

(2) A statement of concentration of the ingredient in any intermediate mix; or other information to permit a food processor independently to determine that use of the ingredients will be in accordance with any limitations and good manufacturing practice gudelines prescribed.

(3) Adequate directions for use to provide a final food product that complies with any limitations prescribed for the ingredient(s).

[42 FR 14653, Mar. 15, 1977, as amended at 42 FR 55205, Oct. 14, 1977; 48 FR 48457, 48459, Oct. 19, 1983; 62 FR 15110, Mar. 31, 1997]

Subpart B—Listing of Specific Substances Affirmed as GRAS

§184.1005 Acetic acid.

(a) Acetic acid ($C_2H_4O_2$, CAS Reg. No. 64–19–7) is known as ethanoic acid. It